

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ERRANT GENE THERAPEUTICS, LLC,	)	
	)	
Plaintiff,	)	
	)	C.A. No.
v.	)	
	)	<b>JURY TRIAL DEMANDED</b>
BLUEBIRD BIO, INC.,	)	
	)	
Defendant.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Errant Gene Therapeutics, LLC (“EGT”), for its Complaint against Defendant Bluebird Bio, Inc. (“Bluebird” or “Defendant”), hereby alleges, on knowledge as to its own actions, and upon information and belief as to all other matters, as follows:

**NATURE OF THE CASE**

1. This is an action for infringement of U.S. Patent Nos. 7,541,179 (“the ’179 Patent”) and 8,058,061 (“the ’061 Patent”) (collectively, the “Patents-in-Suit”) pursuant to the Patent Laws of the United States, 35 U.S.C. §1, *et seq.*

2. EGT has an exclusive commercial license to the ’179 and ’061 Patents, titled “Vector Encoding Human Globin Gene And Use Thereof In Treatment of Hemoglobinopathies,” which claim recombinant vectors that are used in the treatment of hemoglobinopathies, such as Sickle Cell Disease and Beta Thalassemia.

3. EGT is a biopharmaceutical company, established in 1993 by its founder and Chief Executive Officer, Mr. Patrick Girondi, after his son was diagnosed with Beta Thalassemia, a rare inherited blood disorder. Since that time, and for the greater part of nearly two decades, EGT has dedicated itself to developing treatments for life-threatening diseases, with a special focus on rare diseases (commonly referred to as orphan diseases), through the use of gene therapy — a scientific

technique that treats genetic disorders by modifying, replacing, and/or inactivating mutated genes responsible for causing the disease.

4. As a result of its tireless efforts, EGT has successfully developed recombinant vectors that can be used in gene therapy treatment of rare genetic diseases, such as Sickle Cell Disease and Beta Thalassemia (also referred to as  $\beta$ -thalassemia). Indeed, EGT became the first company to obtain Orphan Drug Designation for Beta Thalassemia in the United States and Europe, and the first to produce a commercial batch (sufficient for 8-10 patients) of gene therapy for Beta Thalassemia.

5. EGT brings this action to protect its rights and investment in its innovations embodied in the '179 and '061 Patents infringed by Bluebird's betibeglogene autotemcel (beti-cel) drug product (marketed as ZYNTEGLO® and LENTIGLOBIN®), which is manufactured using (and containing) the BB305 lentiviral vector (hereafter "the BB305 Vector" or "Infringing Drug Product").

### **THE PARTIES**

6. EGT is a Delaware limited liability company with its principal place of business at 308 East Emily Street, Tampa, Florida 33603.

7. Bluebird is a Delaware corporation with business offices located at 60 Binney Street, Cambridge, Massachusetts 02142, and at 188 East Blaine Street, Suite 300, Seattle, Washington 98102.

### **JURISDICTION AND VENUE**

8. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*

9. This Court has subject matter jurisdiction over the matters asserted herein pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Bluebird at least because Bluebird is incorporated in the State of Delaware.

11. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a), 1391(c), and 1400(b) because Bluebird is incorporated in this District and therefore “resides” in this District.

### **THE PATENTS-IN-SUIT**

12. On June 2, 2009, the United States Patent and Trademark Office (“USPTO”) duly and legally issued the ’179 Patent, entitled “Vector Encoding Human Globin Gene and Use Thereof in Treatment of Hemoglobinopathies,” to Michel Sadelain, Stefano Rivella, Chad May, and Joseph Bertino, and the ’179 Patent was assigned to Memorial Sloan Kettering Cancer Center (“MSKCC”). A true and correct copy of the ’179 Patent is attached as Exhibit A.

13. The ’179 Patent issued from U.S. Patent Application No. 10/188,221, which claims priority to Provisional Application Nos. 60/301,861 filed on June 29, 2001 and 60/302,852 filed on July 2, 2001.

14. On November 15, 2011, the USPTO issued the ’061 Patent, entitled “Vector Encoding Human Globin Gene and Use Thereof in Treatment of Hemoglobinopathies,” to Michel Sadelain, Stefano Rivella, Chad May, and Joseph Bertino, and the ’061 Patent was assigned to MSKCC. A true and correct copy of the ’061 Patent is attached as Exhibit B.

15. The ’061 Patent issued from U.S. Patent Application No. 12/433,412, which is a division of Application No. 10/188,221 filed on July 1, 2002, now the ’179 Patent. The ’061 Patent

claims priority to Provisional Application Nos. 60/301,861 filed on June 29, 2001 and 60/302,852 filed on July 2, 2001.

**EGT has an Exclusive Commercial License  
to the '179 and '061 Patents**

16. MSKCC granted EGT an exclusive (worldwide) commercial license to the intellectual property listed in a March 7, 2005 Exclusive License Agreement (the “2005 Agreement”). MSKCC neither retained nor has any substantial rights to the Patents-in-Suit.

17. The intellectual property licensed in the 2005 Agreement is set forth under Exhibit A thereto, and includes: U.S. Patent Application No. 10/188,221, filed on July 1, 2002, “Vector Encoding Human Globin Gene and Use thereof in Treatment of Hemoglobinopathies;” U.S. Provisional Applications Nos. 60/301,861, filed on June 29, 2001 and 60,302,852 filed on July 2, 2001; and International Application No. PCT/US2002/020988.

18. The 2005 Agreement further provides that the patent rights shall mean all of the following intellectual property: (a) the United States and foreign patents and patent applications listed in Exhibit A; (b) the United States and foreign patents issued from the applications listed in Exhibit A and from divisionals and continuations of these applications; (c) claims of U.S. and foreign continuation-in-part applications, and of the resulting patents, which are directed to the subject matter specifically described in the U.S. and foreign patent applications listed in Exhibit A; and (d) any reissues or re-examinations of patents described in (a), (b), or (c), above.

19. The '179 Patent issued from U.S. Patent Application No. 10/188,221, which is listed in Exhibit A to the 2005 Agreement. The '061 Patent is a Division of U.S. Application No. 10/188,221 filed on July 1, 2002, now the '179 Patent. The '179 and '061 Patents claim priority to U.S. Provisional Application Nos. 60/301,861 and 60/302,852, which are listed in Exhibit A to the 2005 Agreement.

20. EGT has an exclusive (worldwide) commercial license to any process, service, or any product, or part thereof made, used or sold that is covered by any claim of the '179 Patent and/or the '061 Patent for any field of use.

21. EGT has an exclusive (worldwide) commercial license to any process, service, or any product, or part thereof made, used, or sold that is manufactured by using a process covered by any claim of the '179 and/or the '061 Patent for any field of use.

22. As the exclusive (worldwide) commercial licensee having all substantial rights in the Patents-in-Suit, EGT has the primary responsibility for enforcing the patent rights to the '179 and '061 Patents.

23. As the exclusive (worldwide) commercial licensee, EGT has standing to bring this action in its own name, without joining MSKCC, because “all substantial rights” in the Patents-in-Suit were transferred to EGT pursuant to its exclusive (worldwide) commercial license to the Patents-in-Suit.

24. As the exclusive (worldwide) commercial licensee, EGT has the constitutional right under the Patents-in-Suit to exclude Bluebird from engaging in its infringing activity and conduct which has injured EGT.

**BLUEBIRD INFRINGES THE '179 AND '061 PATENTS**  
**AND IS DOING SO WILLFULLY**

25. With respect to the BB305 Vector, Bluebird is engaging in infringing activities that are outside the scope of 35 U.S.C. § 271(e)(1), and its activities are not solely for uses reasonably related to the development and submission of information to the U.S. Food and Drug Administration (“FDA”).

26. In 2015, the FDA granted Breakthrough Therapy designation to Bluebird’s Infringing Drug Product for the treatment of transfusion-dependent patients with Beta

Thalassemia, which is intended to expedite the development and review of the Infringing Drug Product and includes the same benefits as Fast Track designation. *See* Exhibit C (“FDA Grants Breakthrough Therapy Designation to LentiGlobin for Treatment of Beta Thalassemia Major”).

27. In September 2021, Bluebird completed the submission of its Biologics License Application (“BLA”) to the FDA for its Infringing Drug Product, which is manufactured using (and containing) the BB305 lentiviral vector. However, Bluebird has engaged and continues to engage in non-regulatory conduct and post-FDA submission activities related to the commercialization of the BB305 Vector, which infringes the ’179 and ’061 Patents.

28. With respect to the BB305 Vector, Bluebird’s employees engage with community and hospital Health Care Providers (“HCPs”) focused on hemoglobinopathies and bone marrow transplant to facilitate consideration of patients for gene therapy and refer appropriate patients to a Bluebird Qualified Treatment Center (“QTC” or “QTCs”).

29. With respect to the BB305 Vector, Bluebird engages in developing go-to-market local and account-based strategies, and in a manner that conditions the market for one-time gene therapies and Bluebird’s first U.S. product launch.

30. With respect to the BB305 Vector, Bluebird’s employees engage in: (i) organizing, and leading market development programs to build awareness of Bluebird’s gene therapy product portfolio, including the BB305 Vector, and provide disease and gene therapy education; (ii) delivering Bluebird’s gene therapy products’ clinical information and reimbursement information to support access to Bluebird’s portfolio; and (iii) advancing and deepening relationships with professional local/regional opinion leaders, QTC staff, hospital administrators, and other relevant external stakeholders that are essential partners in creating opportunities for patients.

31. With respect to the BB305 Vector, Bluebird's employees currently engage in: (i) building and executing a comprehensive account plan for QTCs, referral networks, and community practices and managing approved resources; (ii) partnering with market access, patient services, marketing, field medical affairs, and other internal Bluebird team members to ensure HCPs and other account-based decision-makers have timely access to clinical, health, economic, and outcome research information; and (iii) participating in patient advocacy, outreach, and identification with local advocacy organizations.

32. With respect to the BB305 Vector, Bluebird's employees have (i) attended conferences to promote the BB305 Vector and (ii) implemented the company's Sickle Cell Disease strategic sales plan for the BB305 Vector.

33. Bluebird is currently engaged in expanding its U.S. commercial manufacturing capabilities for the BB305 Vector. According to its corporate statements, Bluebird is committed to investing in the capabilities and infrastructure necessary to support commercialization both in the U.S. and Europe, which includes commercialization of the BB305 Vector. *See* Exhibit D ("bluebird bio and apceth Biopharma Establish Commercial Drug Product Manufacturing Agreement").

34. Bluebird is engaging in stock-piling, ramp-up manufacturing, commercial manufacturing, marketing, and other commercialization activities for the BB305 Vector that are not reasonably related to obtaining FDA approval.

35. Bluebird has made (and continues to make) batches of the BB305 Vector that were used (and will continue to be used) for other business purposes, and which are not manufactured for use by Bluebird for FDA purposes.

36. Bluebird made batches of the BB305 Vector for use in manufacturing capacity development and yield optimization for purposes of commercialization of the BB305 Vector drug product.

37. Bluebird's Infringing Drug Product was cleared to market in Europe, where it was sold under the brand names LENTIGLOBIN (for Sickle Cell Disease) and ZYNTEGLO (for Beta Thalassemia).

38. In 2017, Bluebird applied for a U.S. trademark registration of the name LENTIGLOBIN in International Class 005 for "Pharmaceutical preparations and substances for the treatment of genetic diseases," and was issued the trademark registration by the USPTO in 2019, and maintains that registration with the USPTO.

39. In 2019, Bluebird applied for a U.S. trademark registration of the name ZYNTEGLO in International Class 005 for "pharmaceutical preparations and substances for the treatment of genetic diseases" and in International Class 042 for "pharmaceutical research and development," and was issued the trademark registration by the USPTO in 2020, and maintains that registration with the USPTO.

40. In 2019, Bluebird applied for a U.S. trademark registration of the ZYNTEGLO<sup>TM</sup> logo in International Class 005 for "pharmaceutical preparations and substances for the treatment of genetic diseases," and was issued the trademark registration by the USPTO in 2020, and maintains that registration with the USPTO.

41. With respect to the BB305 Vector, Bluebird has marketed development programs to build awareness of the BB305 Vector, and provided marketing information related to the BB305 Vector's clinical information and reimbursement information to HCPs.



42. Bluebird has engaged in developing and is currently partnered with QTCs for the treatment of patients with the BB305 Vector in the commercial setting in anticipation of obtaining FDA approval of the BB305 Vector.

43. With respect to the BB305 Vector, Bluebird has established commercial drug product manufacturing agreements with contract development and manufacturing companies in the field of cell and gene therapy, such as, for example, apceth Biopharma GmbH, Brammer Bio, Novasep, and SAFC Carlsbad, Inc. *See, e.g.*, Exhibit E (bluebird bio, Inc. Form 10-K, dated Feb. 21, 2019 at 17).

44. Bluebird uses a commercial manufacturing facility in Durham, North Carolina for ramping up manufacturing and stock-piling the BB305 Vector. The Durham facility produces clinical and commercial supplies of the BB305 Vector on behalf of Bluebird. *See, e.g.*, Exhibit F (“bluebird bio Opens State-of-the-Art Gene and Cell Therapy Manufacturing Facility in Durham, North Carolina”).

45. In addition, Bluebird has multi-year agreements with manufacturing partners in the United States and Europe (*e.g.*, Brammer Bio, Novasep and SAFC Carlsbad, Inc.) for commercial production of the BB305 Vector, including the importation of the infringing BB305 Vector drug product. *See, e.g.*, Exhibit G (bluebird bio, Inc. Form 10-K, dated Feb. 23, 2021 at 93).

46. In June 2016, Bluebird entered into a strategic manufacturing agreement with Lonza Houston, Inc. for the commercial production of Bluebird’s BB305 Vector. Under this agreement, Lonza is currently conducting process validation for the commercial batches of Bluebird’s BB305 Vector prior to its anticipated commercial launch. *See, e.g.*, Exhibit H (bluebird bio, Inc. Collaborations).

47. In May 2020, Bluebird expanded its manufacturing agreement with Minaris Regenerative Medicine GmbH (“Minaris”) to provide for commercial drug product manufacturing in both the United States and Europe for the BB305 Vector. *See, e.g.*, Exhibit H; *see also* Exhibit G at 9.

48. In addition, Bluebird relies on specialized third-party testing organizations to confirm the quality of the BB305 Vector in the commercial context. *See, e.g.*, Exhibit G at 9.

49. Bluebird’s arrangements with its manufacturing partners were specifically designed to support the commercialization of the BB305 Vector.

50. In its agreements, Bluebird’s manufacturing partners are required to provide rolling forecasts for the BB305 Vector on a quarterly basis, a portion of which will be considered binding, firm orders, subject to a purchase commitment. *See* Exhibit G at 9.

51. Bluebird has made systematic attempts to meet U.S. regulatory requirements to obtain marketing approval for its BB305 Vector drug product.

52. Bluebird’s current commercialization and other business activities, including the production of batches of the BB305 Vector, are specifically for business purposes, and as such, Bluebird infringes the Patents-in-Suit.

**EGT Has Suffered Irreparable Harm in Excess of Two Billion Dollars  
as a Result of Bluebird’s Willful Infringement**

53. EGT has diligently worked since 2005 and expended substantial sums of money for the development of vectors in collaboration with Drs. Michel Sadelain and Stefano Rivella, the inventors of the Patents-in-Suit.

54. In 2000, EGT began financially supporting the research of Drs. Michel Sadelain and Stefano Rivella, both of whom were researchers at MSKCC, and had published a paper on their experiments with gene therapy for treating Beta Thalassemia in mice.

55. EGT's tireless efforts, and work with Dr. Sadelain and others, resulted in the development of the TNS9.3.55 vector (the "TNS9 Vector") for the treatment of Beta Thalassemia.

56. EGT committed every available resource at its disposal to produce the TNS9 Vector — what became trademarked by EGT as THALAGEN® — in accordance with the FDA's stringent approval process for investigational new drugs ("IND").

57. In addition, EGT, through various industrial research agreements with MSKCC and other top medical centers, diligently continued testing and refining the TNS9 Vector to ensure patient safety conformance with the highest manufacturing and testing standards, designated by the FDA as chemical Good Manufacturing Practice ("cGMP").

58. In 2007, EGT became the first entity to pass the FDA Recombinant DNA Committee for gene therapy in Beta Thalassemia (and future applications in Sickle Cell Disease). In 2008, EGT successfully requested a pre-IND meeting with the FDA to advance to clinical (*i.e.*, human) trials, the next stage necessary to develop the TNS9 Vector. On September 1, 2010, EGT completed the manufacture and production of a batch of the TNS9 Vector in an amount sufficient to treat 8-10 patients in a Phase I clinical trial.

59. Mr. Patrick Girondi, the founder and CEO of EGT, is the father of a Beta Thalassemia patient. EGT's goal is to make gene therapy accessible for all patients. EGT's gene therapy product is projected to cost much less — ***over 1 million dollars less*** — per patient than Bluebird's Infringing Drug Product, which is projected to cost over 2 million dollars per patient.

60. EGT has an exclusive worldwide right and license to the '179 and '061 Patents, including the right to sublicense and/or practice the methods embodied by the '179 and/or '061 Patents to make, have made, use, lease and sell, import and otherwise dispose of any Vector (or licensed product) covered by the '179 and/or '061 Patents.

61. Bluebird had knowledge of the '179 and '061 Patents as of their date of issuance and that its BB305 Vector infringes the '179 and '061 Patents.

62. Bluebird identified and cited U.S. Publication No. 2009/0274671 for the Patents-in-Suit as prior art to Bluebird's U.S. Patent No. 9,783,822, titled "Gene Therapy," which was filed in January 2015.

63. Bluebird has had actual knowledge that EGT has an exclusive (worldwide) commercial license to the '179 and '061 Patents since no later than November 2020.

64. At a minimum, Bluebird was willfully blind that the BB305 Vector infringes the '179 and '061 Patents, and acted, despite a risk of infringement, that was either known, or so obvious, to Bluebird that Bluebird should have known that its BB305 Vector infringes the '179 and '061 Patents.

65. Bluebird's willful infringement of the Patents-in-Suit has damaged EGT. EGT is entitled to recover damages sustained as a result of Bluebird's past and present wrongful infringing acts in an amount to be determined at trial.

66. Given the imminent and irreparable harm, EGT seeks a permanent injunction and may seek a preliminary injunction to stop Bluebird from continuing the infringement of EGT's patent rights and from making, having made, using, importing, selling, or offering for sale the BB305 Vector in the United States. EGT also seeks past damages of no less than a reasonable royalty, which includes milestone payments based upon a hypothetical negotiation, and enhanced damages due to Bluebird's willful misconduct.

**FIRST CAUSE OF ACTION**  
**Infringement of the '179 Patent**

67. EGT repeats, realleges, and incorporates by reference the allegations in paragraphs 1 through 66 as if fully set forth herein.

68. EGT has an exclusive commercial license to the vectors that are within the scope of the claims of the '179 Patent.

69. Bluebird, directly or indirectly, infringes a valid claim of the '179 Patent, either literally or under the doctrine of equivalents.

70. The '179 Patent covers recombinant lentiviral vectors having a region encoding a functional  $\beta$ -globin gene; and large portions of the  $\beta$ -globin locus control regions ("LCR"), which include DNase I hypersensitive sites HS2, HS3, and HS4, and provide expression of  $\beta$ -globin when introduced into a mammal, for example a human, in vivo.

71. Claim 1 of the '179 Patent is directed to a recombinant vector comprising a nucleic acid encoding a functional globin operably linked to a 3.2-kb nucleotide fragment which consists essentially of three contiguous nucleotide fragments obtainable from a human  $\beta$ -globin LCR, the three fragments being a BstXI and SnaBI HS2-spanning nucleotide fragment of said LCR; a BamHI and HindIII HS3-spanning nucleotide fragment of said LCR; and a BamHI and BanII HS4-spanning nucleotide fragment of said LCR, said vector providing expression of the globin in a mammal in vivo.

72. Claim 23 of the '179 Patent is directed to a recombinant vector comprising a nucleic acid encoding a functional globin operably linked to a 3.2-kb nucleotide fragment which consists essentially of three nucleotide fragments obtainable from a human  $\beta$ -globin LCR, the three fragments being a BstXI and SnaBI, HS2-spanning nucleotide fragment of said LCR; a BamHI and HindIII, HS3-spanning nucleotide fragment of said LCR; and a BamHI and BanII, HS4-

spanning nucleotide fragment of said LCR, wherein the HS3-spanning nucleotide fragment and the HS4-spanning nucleotide fragment are adjacent to each other and the vector further comprises 2 GATA-1 binding sites at the junction between the HS3-spanning and HS4-spanning nucleotide fragments, said vector providing expression of the globin in a mammal in vivo.

73. As demonstrated in the '179 Patent claim chart (*see* Exhibit I), Bluebird's BB305 Vector infringes at least claims 1 and 23 of the '179 Patent, either literally or under the doctrine of equivalents.

74. Bluebird has committed and continues to commit these acts of infringement of the '179 Patent without license or authorization.

75. As a result of Bluebird's infringement of the '179 Patent, EGT has suffered damages and will continue to suffer damages, including damages awardable under 35 U.S.C. §§ 284 and 285.

76. Bluebird's infringement of the '061 Patent has been willful and continues to be willful. Bluebird has had and currently has knowledge of its infringement of the '061 Patent, including at least for the reason that, in 2011, Bluebird had discussions with the inventors and MSKCC involving the identification of potential areas of collaboration, including vector design and next-generation Sickle Cell Disease and Beta Thalassemia vectors. Bluebird continued to infringe despite having knowledge of its infringement or being willfully blind to its infringement.

77. Bluebird's infringing conduct has caused and is causing irreparable harm to EGT for which EGT has no adequate remedy at law, and such irreparable harm will continue unless and until Bluebird is enjoined by this Court.

**SECOND CAUSE OF ACTION**  
**Infringement of the '061 Patent**

78. EGT repeats, realleges, and incorporates by reference the allegations in paragraphs 1 through 77 as if fully set forth herein.

79. EGT has an exclusive (worldwide) commercial license to the vectors that are within the scope of the claims of the '061 Patent.

80. Bluebird, directly or indirectly, infringes a valid claim of the '061 Patent, either literally or under the doctrine of equivalents.

81. The '061 Patent covers recombinant lentiviral vectors having a region encoding a functional  $\beta$ -globin gene; and large portions of the  $\beta$ -globin LCR, which include DNase I hypersensitive sites HS2, HS3 and HS4, and provide expression of  $\beta$ -globin when introduced into a mammal, for example a human, in vivo.

82. Claim 1 of the '061 Patent is directed to an isolated mammalian hematopoietic progenitor cell or an isolated mammalian stem cell comprising a recombinant lentiviral vector.

83. Claim 11 of the '061 Patent is directed to a method of making a mammalian hematopoietic progenitor cell or a mammalian stem cell.

84. As demonstrated in the '061 Patent claim chart (*see* Exhibit J) the BB305 Vector infringes at least claims 1-2, 5, 7-8, 11 and 15 of the '061 Patent, either literally or under the doctrine of equivalents.

85. Bluebird has committed and continues to commit these acts of infringement of the '061 Patent without license or authorization.

86. As a result of Bluebird's infringement of the '061 Patent, EGT has suffered damages and will continue to suffer damages, including damages awardable under 35 U.S.C. §§ 284 and 285.

87. Bluebird's infringement of the '061 Patent has been willful and continues to be willful. Bluebird has had and currently has knowledge of its infringement of the '061 Patent, including at least for the reason that, in 2011, Bluebird had discussions with the inventors and MSKCC involving the identification of potential areas of collaboration, including vector design and next-generation Sickle Cell Disease and Beta Thalassemia vectors. Bluebird continued to infringe despite having knowledge of its infringement or being willfully blind to its infringement.

88. Bluebird's infringing conduct has caused and is causing irreparable harm to EGT for which EGT has no adequate remedy at law, and such irreparable harm will continue unless and until Bluebird is enjoined by this Court.

#### **PRAYER FOR RELIEF**

WHEREFORE, EGT respectfully requests that the Court enter judgment in its favor and against Bluebird as follows:

A. Enter judgment that Bluebird has infringed, and continues to infringe a valid claim of the '179 and '061 Patents, either literally or under the doctrine of equivalents;

B. Enter judgment that Bluebird's making, having made, using, importing, selling or offering to sell, the BB305 Vector infringes, at least, claims 1 and 23 of the '179 Patent, either directly or under the doctrine of equivalents;

C. Enter judgment that Bluebird's making, having made, using, importing, selling or offering to sell the BB305 Vector infringes, at least, claims 1-2, 5, 7-8, 11 and 15 of the '061 Patent, either directly or under the doctrine of equivalents;

D. Permanently enjoin Bluebird, its officers, employees, agents, representatives, attorneys, and others acting on its behalf from engaging in any activity that is not solely for uses reasonably related to its BLA for the BB305 Vector submitted to the FDA until after expiration of the '179 and '061 Patents;



E. Permanently enjoin Bluebird, its officers, employees, agents, representatives, attorneys, and others acting on its behalf from engaging in any commercialization activities related to the BB305 Vector, including barring Bluebird from making, having made, marketing, distributing, offering to sell, or selling the BB305 Vector until after expiration of the '179 and '061 Patents;

F. Order Bluebird, its officers, employees, agents, representatives, attorneys, and others acting on its behalf to cease any and all marketing and/or commercialization activities related to the BB305 Vector until after expiration of the '179 and '061 Patents;

G. Alternatively, award, in lieu of an injunction, ongoing royalties;

H. Award EGT damages adequate to compensate EGT for both Bluebird's past and present infringement of the Patents-in-Suit, including supplemental damages for any post-verdict infringement up until entry of the final judgment with an accounting as needed, together with interest and costs under 35 U.S.C. § 284;

I. Enter judgment that Bluebird's infringement is willful and that the damages awarded to EGT should be enhanced for up to three times the actual damages awarded;

J. Declare that this case is exceptional and an award to EGT of its costs, expenses, and reasonable attorneys' fees under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon;

K. Award EGT pre-judgment and post-judgment interest; and

L. Award such other and further relief as the Court may deem just and proper under the circumstances.

**DEMAND FOR JURY TRIAL**

Pursuant to Fed. R. Civ. P. 38(b) and D. Del. LR 38.1, EGT hereby demands a trial by jury as to all issues so triable in this case.

Dated: October 21, 2021

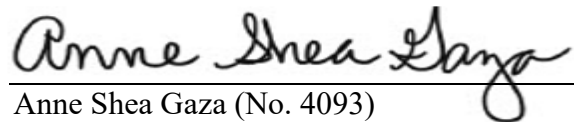
YOUNG CONAWAY STARGATT  
& TAYLOR, LLP

*Of Counsel:*

Wanda D. French-Brown  
Mary Jean Kim  
LOEB & LOEB LLP  
345 Park Avenue  
New York, New York 10154  
(212) 407-4000  
wfrenchbrown@loeb.com  
mjkim@loeb.com

Alexandra Cavazos  
LOEB & LOEB LLP  
10100 Santa Monica Blvd  
Los Angeles, California 90067  
(312) 282-2000  
acavazos@loeb.com

Lenore Horton  
HORTON LEGAL STRATEGIES PLLC  
122 W. 27th Street, 10th Floor  
New York, New York 10001  
(212) 888-9140  
lenore@hortonlegalstrategies.com

A handwritten signature in black ink, reading "Anne Shea Gaza". The signature is fluid and cursive, with a horizontal line drawn underneath it.

Anne Shea Gaza (No. 4093)  
Samantha G. Wilson (No. 5816)  
Rodney Square  
1000 North King Street  
Wilmington, DE 19801  
(302) 571-6600  
agaza@ycst.com  
swilson@ycst.com

*Attorneys for Plaintiff*  
*Errant Gene Therapeutics, LLC*